70. A vector comprising an HIV-1 DNA fragment, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

71. The vector of claim 70, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

72. A host cell transformed with a vector comprising an HIV-1 DNA fragment, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

73. The host cell of claim 72, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.--

REMARKS

Applicants respectfully request reconsideration of this application.

Claims 39-52 are allowed. Claims 53-59 have been canceled. Applicants have amended claims 60 and 61 to depend upon allowed claims 46-52. Applicants submit that claims 60 and 61 are now allowable, as indicated by the Examiner. (Paper No. 26 at 5). Claims 62-73 are new and are fully supported by the specification, for example, as described below.

The specification teaches that "The DNAs according to the invention consist of DNAs which contain DNA fragments, hybridizable with the genomic RNA of LAV." (*Id.* at 2, paragraph 3). The specification teaches the cloning of HIV-1 fragments and genomic DNA. (*Id.* at 5-11). The specification teaches that λJ19 and λJ81 are genomic clones of HIV-1 DNA. (*Id.* at 9-11). The specification teaches restriction maps of the entire HIV-1 genome. (*Id.* at 4 and

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Fig. 2). The specification teaches that all of the *Hind*III restriction fragments of λJ81 DNA hybridize under stringent hybridization and washing conditions to λJ19 DNA. (*Id.* at 11, paragraph 1). Therefore, the skilled artisan would recognize that the invention encompasses DNA fragments, consisting of restriction fragments, which hybridize to HIV-1 genomic DNA, as recited in claim 62.

The specification teaches that "The invention relates to cloned DNA sequences hybridizable to genomic RNA and DNA of lymphadenopathy-associated virus (LAV) . . . . " (Specification at 1, paragraph 1). Therefore, the skilled artisan would recognize that the invention encompasses cloned DNAs, which hybridize to HIV-1 genomic DNA, as recited in claim 64.

The specification teaches the generation of double-stranded HIV-1 cDNA fragments and their insertion into a vector. (*Id.* at 6, paragraphs 2-6). First, a single-stranded DNA copy of HIV-1 RNA was generated and purified. (*Id.* at 6, paragraphs 2-5). Then, the single-stranded DNA copy was made double-stranded. (*Id.* at 6, paragraph 6). The double-stranded DNA copies were inserted into a vector and transformed into bacteria. (*Id.* at 6, paragraphs 6-7). Recombinant clones were screened for the presence of HIV-1 DNA and individual clones were identified and their inserts were characterized by hybridization. (*Id.* at 7-8). It was found that the clones were copies of the 3' end of a polyA-RNA. (*Id.* at 8, paragraph 3). Therefore, the skilled artisan would recognize that the invention encompasses isolated double-stranded HIV-1 DNA fragments, as recited in claim 66.

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The specification teaches specific cDNA fragments, and that these fragments contain restriction enzyme sites. (*Id.* at 2, paragraph 4, and Figs. 1 and 2). The specification further teaches that cDNA fragments may be in isolated form or in a plasmid. (*Id.* at 3, paragraph 1). Therefore, the skilled artisan would recognize that the invention encompasses HIV-1 DNA fragments in a vector, as recited in claim 70.

The specification teaches the cloning of HIV-1 fragments and genomic DNA. (*Id.* at 5-11). Genomic clones λJ19 and λJ81 were deposited at the C.N.C.M. on September 11, 1984. (*Id.* at 14, paragraph 5). The specification teaches that the DNA insert of pLAV13 hybridizes to λJ19. (*Id.* at 9-10). The specification teaches that all of the *Hind*III restriction fragments of λJ81 DNA hybridize under stringent hybridization and washing conditions to λJ19 DNA. (*Id.* at 11, paragraph 1). Therefore, the skilled artisan would recognize that the invention encompasses isolated and cloned HIV-1 DNA fragments, which hybridize to λJ19 DNA, as recited in claims 63, 65, 67, 69, 71, and 73.

The specification teaches the generation of a single-stranded DNA copy of HIV-1 RNA, and subsequent generation of a double-stranded DNA copy. (*Id.* at 7). The specification teaches the insertion of this DNA into a vector and the small-scale amplification of clones containing HIV-1 fragments. (*Id.* at 7-8). The amplified inserts were analyzed by hybridization. (*Id.* at 8). It was found that the clones were copies of the 3' end of a polyA-RNA. (*Id.* at 8, paragraph 3). Therefore, the skilled artisan would recognize that the invention encompasses amplified copies of HIV-1 DNA fragments, as recited in claim 68.

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The specification teaches restriction maps of the entire HIV-1 genome. (*Id.* at 4 and Fig. 2). The specification further teaches that all of the *Hind*III restriction fragments of λJ81 DNA hybridize under stringent hybridization and washing conditions to λJ19 DNA. (*Id.* at 11, paragraph 1). Therefore, the skilled artisan would recognize that the invention encompasses isolated or cloned HIV-1 fragments, which hybridize to λJ19 DNA under stringent hybridization and washing conditions.

The specification teaches that λJ19 DNA, even when hybridized in 20% formamide, 8XSSC and washed at 37°C, in 2X SSC, did not cross-hybridize with HTLV-II DNA. (*Id.* at 11, paragraph 3). The specification also teaches that HIV-1 DNA, did not cross-hybridize with Visna cloned viral genomes or human endogenous viral genomes under non-stringent conditions. (*Id.* at 12, paragraph 1). The specification teaches that these non-stringent conditions were hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C. (*Id.* at 12, paragraph 1). The skilled artisan would recognize that HTLV-II DNA, Visna cloned viral genomes, and human endogenous viral genomes would also not cross-hybridize under stringent conditions.

The skilled artisan would further recognize that, under the recited non-stringent conditions, HIV-1 genomic DNA would hybridize with HIV-1 genomic DNA, and fragments thereof. The skilled artisan would also recognize that the results indicating a lack of "cross-hybridization" implicitly teach that "self-hybridization" occurs under these conditions since "cross-hybridization" would not be measurable if "self-hybridization" did not occur.

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Applicants note that, as detailed above, the specification teaches that restriction fragments of λJ81 DNA hybridize under stringent hybridization and washing conditions to λJ19 DNA. The skilled artisan would not expect that the use of non-stringent, as opposed to stringent, conditions would decrease detection of hybridizing HIV-1 fragments. Rather, the skilled artisan would expect increased detection under non-stringent conditions. Therefore, the skilled artisan would recognize that hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C, as recited in claims 62, 64, 66, 68, 70, and 72, were hybridization and washing conditions encompassed by the claimed invention.

The specification teaches that the invention encompasses prokaryotic or eukaryotic host cells, which are transformed by recombinant vectors containing HIV-1 DNA fragments. (*Id.* at 13-14). Therefore, the skilled artisan would recognize that the invention encompasses host cells transformed with vectors containing HIV-1 DNA fragments, as recited in claim 72.

No new matter enters by amendment. Upon amendment, claims 39-52 and 60-73 are pending in this application.

Claims 53-61 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter, which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the Examiner contends that hybridization conditions are discussed in reference to hybridization between LAV cDNA clones and HTLV-II DNA. The Examiner further contends that the claims encompass an exceedingly large genus of nucleic acids, and that the specification does not provide restriction maps or

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nucleotide sequences from other HIV-1 isolates and fails to describe hybridization assays with other HIV-1 clones. The Examiner contends that skilled artisan would not conclude that applicants contemplated isolating and purifying the claimed restriction fragments. Applicants traverse the rejection.

Applicants have canceled claims 53-59 and added new claims 62-73. Applicants submit that claims 62-73 fulfill the written description requirement of 35 U.S.C. § 112, first paragraph.

In order to determine the appropriate disclosure of an application, the specification as a whole must be considered. *In re Wright*, 866 F.2d 422, 424, 9 U.S.P.Q. 2d 1649, 1651 (Fed. Cir. 1989). Furthermore, there is no particular way in which the disclosure must convey the required information to one skilled in the art. *Id.* Thus, one must peruse the full scope of the disclosure, the working examples, the stated objectives, and all of the embodiments in order to determine whether in some way the written description conveys the invention to one skilled in the art. When this is done for the full disclosure in this case, applicants' specification meets the written description requirement of 35 U.S.C. § 112, first paragraph. For the reasons cited above relating to the support in the specification for new claims 62-73, applicants submit that, when the specification is considered **as a whole**, applicants have fully described the claimed invention.

Furthermore, applicants respectfully submit that the Examiner is not using the appropriate legal standard for determining compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants submit that the test is not whether applicants contemplated making and using every possible species within the claimed genus. Rather, the proper test is whether the specification conveys with reasonable clarity to one skilled in the art that applicants

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had possession of the claimed invention as of the filing date. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q. 2d 1111, 1117 (Fed. Cir. 1991).

Applicants submit that the specification provides the requisite written description to convey to the skilled artisan that applicants possessed the claimed genus as of the filing date. Applicants further submit that the determination of the sufficiency of the applicants' written description must take into account what would have been conveyed to the skilled artisan at the time the application was filed. As detailed below, at the time the application was filed, the skilled artisan did not know the extent of the genotypic variability of HIV-1. Applicants' LAV isolate was a prototype strain of HIV-1. At that time, the skilled artisan would have considered that applicants' description of cloned LAV genomic DNA and hybridization conditions, as detailed above, was an adequate description of the claimed genus. Consequently, the skilled artisan would have had no reason to doubt that applicants were in possession of the claimed genus at the time the application was filed. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 53-61 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable the skilled artisan to make and/or use the invention commensurate in scope with the claims. The Examiner contends that the specification does not disclose, *ipsis verbis*, HIV/LAV viral clones or restriction fragments obtained from any other viral isolates that are capable of hybridizing under the claimed conditions. The Examiner alleges that the specification fails to provide adequate guidance, and concludes that undue experimentation would be required to practice the claimed invention. Specifically, the Examiner

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contends that the disclosure fails to provide an adequate written description of nucleic acids from any other HIV-1 isolate, and only details the isolation of a small number of clones derived from a single HIV-1 isolate. The Examiner concludes that a sufficient number of working embodiments is not provided to enable the breadth of the claimed invention, and that the mere recitation of a small number of species is insufficient to provide adequate support for a large genus of compounds, particularly in unpredictable arts. The Examiner relies upon the disclosures of Goodenow et al., Holland et al., and Gao et al. as "prior art" to demonstrate that the skilled artisan would have been unable to predict the restriction map or nucleotide sequence of any given HIV-1 isolate. The Examiner further contends that the disclosure is deficient as it pertains to a description of structural characteristics of the claimed nucleic acids. Applicants traverse the rejection.

Applicants have canceled claims 53-59 and added new claims 62-73. Applicants submit that claims 62-73 fulfill the enablement requirement of 35 U.S.C. § 112, first paragraph.

Applicants submit that the Examiner has improperly relied on the disclosures of Goodenow et al., Holland et al., and Gao et al. These references were published after applicants' effective filing date. Therefore, Goodenow et al., Holland et al., and Gao et al. cannot be considered "prior art".

Furthermore, later discoveries of unknown variations cannot render the claims non-enabled. *See In re Hogan*, 559 F.2d 595, 605, 194 U.S.P.Q. 527, 537 (C.C.P.A. 1977). Otherwise, the opportunity for obtaining a basic patent upon early disclosure of a pioneer invention would be abolished. *Id.*

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Moreover, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 2d 1510, 1515 (Fed. Cir. 1993). Applicants respectfully submit that the Office has not met this burden, since no evidence has been presented supporting the conclusion that the skilled artisan would have questioned the enablement of the claimed invention **at the time the application was filed.**

As objective evidence of the state of the art at the time the application was filed, applicants submit Arya et al., 1984 (Exhibit 1). On page 929, column 1, paragraphs 3-4, Arya et al. states:

> Retroviruses called LAV (or sometimes $IDAV_1$ and $IDAV_2$) have been isolated from patients with lymphadenopathy and AIDS (*17*). Although LAV has been reported to lack relatedness to HTLV-I and HTLV-II (*17*), further characterization of its proteins may reveal that LAV is related to these viruses and is identical to or related to HTLV-III . . . this virus should be classified within the HTLV family . . . .

Having read this passage from Arya et al., the skilled artisan would have expected that LAV and HTLV-III isolates could be identical.

Furthermore, Arya et al. reported that HTLV-III was related to HTLV-I, and suggested that HTLV-III should be classified within the HTLV family. In the Abstract, Arya et al. states:

> A T lymphotropic virus found in patients with the acquired immune deficiency syndrome (AIDS) or lymphadenopathy syndrome has been postulated to be the cause of AIDS. Immunological analysis of this retrovirus and its biological properties suggest that it is a member of the family of human T-lymphotropic retroviruses known as HTLV. Accordingly, it has been named HTLV-III . . . .

Having read the above passages from Arya et al., the skilled artisan would have expected that HTLV-III and LAV were members of the HTLV family.

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Applicants also submit Barre-Sinoussi et al., 1983 (Exhibit 2), and Schupbach et al, 1984 (Exhibit 3), as objective evidence of the state of the art at the time the application was filed. Applicants submit that these references indicate that, at the time the application was filed, the skilled artisan would have expected that HTLV-III and LAV were most closely related to HTLV-I and HTLV-II and were members of the HTLV family.

In the Abstract, Barre-Sinoussi et al. states:

> A retrovirus belonging to the family of recently discovered human T-cell leukemia viruses (HTLV), but clearly distinct from each isolate, has been isolated from a Caucasian patient with signs and symptoms that often precede the acquired immune deficiency syndrome (AIDS) . . . it is concluded that this virus as well as the previous HTLV isolates belong to a general family of T-lymphotropic viruses . . . .

Similarly, in the Abstract, Schrumpbach et al. states "HTLV-III is thus a true member of the HTLV family." Having read these passage from Barre-Sinoussi et al. and Schrumpbach et al., the skilled artisan would have expected that LAV and HTLV-III were members of the HTLV family. Therefore, the skilled artisan would have expected that LAV and HTLV-III would have properties similar to other members of the HTLV family.

At the time the application was filed, independent isolates of HTLV-I virus had been shown to be highly conserved. For example, on page 627, column 2, second paragraph, Wong-Staal et al.,1983 (Exhibit 4), reported:

> [T]he HTLV genomes as present in patients from Japan, USA, Israel, Brazil and the Carribean all contain an internal 1.05-kb *Bam*HI fragment and a 2.6-kb *Pst*I fragment as detected by the HTLV env-pol probe. This result indicates that the different HTLV strains of subgroup I are highly conserved throughout many geographical regions . . . .

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Having read this passage from Wong-Staal et al., the skilled artisan would have expected different isolates of HTLV-I to be highly conserved. The skilled artisan would further have expected molecular clones of different isolates of HTLV-I to have highly conserved restriction sites. Consequently, the skilled artisan would have expected the restriction maps and hybridization properties of different isolates of HTLV-I to be highly conserved.

Applicants also submit Reitz et al., 1983 (Exhibit 5), Yoshida et al., 1984 (Exhibit 6), Watanabe et al., 1984 (Exhibit 7), and Shaw et al., 1984 (Exhibit 8), as further objective evidence of the state of the art at the time the application was filed. All of these articles indicate that viruses in the HTLV family were thought to be highly conserved.

Since the skilled artisan would have expected that HTLV-III and LAV were HTLV family members, the skilled artisan would have expected HTLV-III and LAV to have properties similar to HTLV-I. Consequently, **at the time the application was filed**, the skilled artisan would have expected different isolates of HIV-1 to be highly conserved. The skilled artisan would have further expected molecular clones of different isolates of HIV-1 to have highly conserved restriction sites. The skilled artisan would have also expected the restriction maps and hybridization properties of different isolates of HIV-1 to be highly conserved.

At the time the application was filed, the skilled artisan would have had no reason to expect that HIV-1 isolates would show the "considerable genomic variability", which the Examiner contends is shown in the post-filing date publications of Goodenow et al., Holland et al., and Gao et al. Accordingly, Goodenow et al., Holland et al., and Gao et al. are not relevant to the enablement of the claimed invention.

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Applicants were the first to clone and characterize HIV-1 DNA clones. Prior to the cloning of HIV-1, the skilled artisan would have had no reason to expect that HIV-1 isolates would have considerable genotypic variability. Rather, the genotypic variability of HIV-1 was only reported **after** the cloning of the HIV-1 genome and **after** applicant's filing date. Reports of HIV-1 genotypic variability, **subsequent to applicants' filing date**, indicate that it was the cloning of HIV-1 DNA sequences and the subsequent comparison of HIV-1 DNA from various isolates, which led to suggestions of HIV-1 genotypic variability in contrast to the lack of variability in the genomes of other members of the HTLV family. *See e.g.* Shaw et al. at 1168, last column, paragraph 2 (Exhibit 9)("The diversity in the genomic restriction maps of different HTLV-III isolates stands in contrast to the high degree of conservation in the genomes of HTLV-I and HTLV-II."). It would only have been after these reports, that the skilled artisan would have known that different isolates of HIV-1 were not highly conserved.

Applicants submit Montagnier et al., 1985 (Exhibit 10), as further objective evidence that, prior to the cloning of the HIV-1 genome, the skilled artisan would have had no reason to expect that HIV-1 isolates would have considerable genotypic variability. HIV-1 was originally thought to belong to the same group as HTLV-I. Montagnier et al. at 319, last paragraph, through 320, paragraph 2. The question of whether HIV-1 was a member of the HTLV family of viruses could not be determined without the biochemical characterization of the viral nucleic acid, and ultimately the nucleotide sequence. *See Id.* at 322, paragraph 3. It was only after the cloning and characterization of HIV-1 nucleic acid that HIV-1 was found to be very different

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from the HTLVs, and recognized to have features in common with lentiviruses. *See Id.* at 320-321, bridging paragraph. This characterization was reported after applicants' filing date.

Applicants also submit Gallo et al., 1985 (Exhibit 11), as objective evidence that it was the characterization of molecular clones of HIV-1 that led to the discovery of HIV-1 polymorphism. Gallo et al. indicates that evidence that HIV-1 is polymorphic was derived from studies on molecular clones and sequencing of HIV-1 isolates. Gallo et al. at 31, first paragraph. Gallo et al. further indicates that the polymorphism of HIV-1 is in contrast to HTLV-I. *Id.* Applicants submit that Gallo et al. indicates that the polymorphism of HIV-1 was not known until after HIV-1 molecular clones were analyzed. This analysis was reported after applicants' filing date.

However, the later discovery of the genotypic variability of HIV-1, which was unknown to the skilled artisan **at the time the application was filed**, does not render the applicants' claims non-enabled. *See Hogan*, 559 F.2d at 605, 194 U.S.P.Q. at 537. Accordingly, applicants submit that claims 62-73 are fully enabled, and that Goodenow et al., Holland et al., and Gao et al. are not relevant to enablement of the claimed invention.

Applicants further traverse the Examiner's contention that applicants' disclosure is inadequate because it does not provide working examples beyond those of the molecular clones of LAV. As discussed above, there was no reason to expect that other clones of HIV-1 would not be highly conserved with applicants' clones. Therefore, there would have been no reason to expect that applicants' disclosure was not sufficient to describe the entire genus of HIV-1 genomic clones.

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Applicants further submit that the disclosure is not deficient with respect to the description of the structural characteristics of the claimed fragments. Applicants deposited genomic clones λJ19 and λJ81 at the C.N.C.M. on September 11, 1984. (Specification at 14, paragraph 5). Applicants provided detailed restriction maps of the entire HIV-1 genome. (*Id.* at 4 and Fig. 2). The skilled artisan recognizes that fragments of HIV-1 can be generated by digesting HIV-1 genomic DNA with the specified restriction enzymes, or other restriction enzymes known in the art. *See* Roberts, 1980 (Exhibit 12); Danna, 1980 (Exhibit 13). Applicants further provide detailed methods for hybridizing HIV-1 DNA fragments with the genomic DNA of HIV-1. (Specification at 11, paragraph 1). Therefore, applicants submit that the specification fully describes the claimed invention, and that the specification enables the claimed invention commensurate in scope with the claims.

Applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976). Rather, applicants can meet the sufficiency of disclosure through illustrative examples by teaching the skilled artisan to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. *In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q. 2d 1438, 1445 (Fed. Cir. 1991). Applicants submit that the specification teaches the skilled artisan which HIV-1 DNA fragments are within the claimed invention. Accordingly, applicants submit that claims 62-73 are fully enabled and respectfully request withdrawal of the rejection.

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Applicants submit that the application is now in condition for allowance. If the Examiner disagrees, applicants invite the Examiner to contact the undersigned to discuss any remaining issues.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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By: _____
Kenneth J. Meyers
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Dated: July 16, 1999

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